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August 10, 2005

VIA FEDERAL EXPRESS

Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Re: **Citizen Petition**

Dear Sir/Madam:

The undersigned submits this petition pursuant to 21 C.F.R. § 10.30, and in accordance with the regulations at 21 C.F.R. § 314.161(b), for a determination that the listed drugs, PHENERGAN® (Promethazine hydrochloride)12.5mg and 50mg tablets, previously part of NDA No. 007935, were voluntarily withdrawn for safety and effectiveness reasons, as outlined below.

A. Action Requested

This petition requests a determination that the listed drugs, PHENERGAN® (Promethazine hydrochloride) tablets 12.5mg and 50mg, were voluntarily withdrawn by Wyeth Pharmaceuticals, Inc., for reasons other than safety and effectiveness.

B. Statement of Grounds

The reference products, PHENERGAN® tablets 12.5mg and 50mg, have been discontinued by Wyeth Pharmaceuticals, Inc., and are currently listed in the Approved Drug Products with Equivalence Evaluations (the "Orange Book") under "DISCONTINUED DRUG PRODUCT LIST." Tab 1 is a copy of the entry from the Orange Book. However, the 25mg strength of PHENERGAN® tablets remains approved. See Tab 2 from the Orange Book.

FDA will not accept for filing an application that references a discontinued drug. Prior to submitting an application for a discontinued drug, an applicant must obtain from FDA a finding as to whether a discontinued drug was withdrawn for reasons of safety or effectiveness. 21 C.F.R. § 314.161(a). If FDA determines that the drug was not

withdrawn for reasons of safety or effectiveness, FDA shall publish a notice in the Federal Register announcing its conclusion, 21 C.F.R. § 314.161(e), and the application referencing the discontinued drug may then be submitted.

The undersigned has no information suggesting that either the 12.5mg or the 50mg tablet strengths of PHENERGAN® were withdrawn for reasons of safety and effectiveness, and, as the 25mg strength remains approved, there appears to be no safety or efficacy issue with these tablet strengths.

Thus, the undersigned requests that FDA determine that the withdrawal from sale of PHENERGAN® 12.5mg and 50mg tablets was made for reasons other than safety and effectiveness and that, therefore, an abbreviated new drug application may be filed for promethazine HCL 12.5mg and 50mg tablets, pursuant to 21 C.F.R. § 314.122.

C. Environmental Impact

Pursuant to 21 C.F.R. § 25.31(a), action on an ANDA is categorically excluded from the requirements of an environmental assessment or impact statement.

D. Economic Impact

Pursuant to 21 C.F.R. § 10.30(b), economic information is submitted only when requested by the Commissioner. This information will be provided if so requested.

E. Certification

The undersigned certifies, that to the best of his knowledge and belief, this petition includes all information and views on which the petition relies, and that it includes representative data and information known to the petitioner which are unfavorable to the petition.

Respectfully submitted,

SONNENSCHEIN NATH & ROSENTHAL LLP

By: 

Peter S. Reichertz

Filed in triplicate.

Enclosures

TAB 1

Proprietary Name Search Results from "OB_Disc" table for query on "phenergan."

Appl No	Active Ingredient	Dosage Form; Route	Strength	Proprietary Name
008306	CODEINE PHOSPHATE; PHENYLEPHRINE HYDROCHLORIDE; PROMETHAZINE HYDROCHLORIDE	SYRUP; ORAL	10MG/5ML;5MG/5ML;6.25MG/5ML	PHENERGAN VC W/ CODEINE
008306	CODEINE PHOSPHATE; PROMETHAZINE HYDROCHLORIDE	SYRUP; ORAL	10MG/5ML;6.25MG/5ML	PHENERGAN W/ CODEINE
011265	DEXTROMETHORPHAN HYDROBROMIDE; PROMETHAZINE HYDROCHLORIDE	SYRUP; ORAL	15MG/5ML;6.25MG/5ML	PHENERGAN W/ DEXTROMETHORPH.
008604	PHENYLEPHRINE HYDROCHLORIDE; PROMETHAZINE HYDROCHLORIDE	SYRUP; ORAL	5MG/5ML;6.25MG/5ML	PHENERGAN VC
008857	PROMETHAZINE HYDROCHLORIDE	INJECTABLE; INJECTION	25MG/ML	PHENERGAN
008857	PROMETHAZINE HYDROCHLORIDE	INJECTABLE; INJECTION	50MG/ML	PHENERGAN
011689	PROMETHAZINE HYDROCHLORIDE	SUPPOSITORY; RECTAL	50MG	PHENERGAN
008381	PROMETHAZINE HYDROCHLORIDE	SYRUP; ORAL	25MG/5ML	PHENERGAN FORTIS
008381	PROMETHAZINE HYDROCHLORIDE	SYRUP; ORAL	6.25MG/5ML	PHENERGAN PLAIN
007935	PROMETHAZINE HYDROCHLORIDE	TABLET; ORAL	12.5MG	PHENERGAN
007935	PROMETHAZINE HYDROCHLORIDE	TABLET; ORAL	50MG	PHENERGAN

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FDA/Center for Drug Evaluation and Research
Office of Generic Drugs
Division of Labeling and Program Support
Update Frequency:
Orange Book Data - **Monthly**
Generic Drug Product Information & Patent Information - **Daily**
Orange Book Data Updated Through June, 2005
Patent and Generic Drug Product Data Last Updated: August 09, 2005

TAB 2

Proprietary Name Search Results from "OB_Rx" table for query on "phenergan."

Appl No	TE Code	RLD	Active Ingredient	Dosage Form; Route	Strength	Proprietary Name	Applicant
010926	AB	No	PROMETHAZINE HYDROCHLORIDE	SUPPOSITORY; RECTAL	12.5MG	PHENERGAN	WYETH PHARMS INC
010926	AB	Yes	PROMETHAZINE HYDROCHLORIDE	SUPPOSITORY; RECTAL	25MG	PHENERGAN	WYETH PHARMS INC
007935		Yes	PROMETHAZINE HYDROCHLORIDE	TABLET; ORAL	25MG	PHENERGAN	WYETH PHARMS INC

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